

REMARKS

The above amendments and these remarks are responsive to the Office action mailed April 6, 2006. Claims 1-13 are pending in the application. Applicants thank the Examiner for the indication that claims 5-7 and 12 would be allowable if rewritten in independent form. In the Office action claims 1-12 were rejected under 35 U.S.C. § 112, second paragraph. Claims 1-4, 8-11, and 13 were rejected under 35 USC §103(a) as being unpatentable over Mizzy et al. (U.S. Patent No. 3,859,996) in view of Hogan (U.S. Patent No. 6,264,637) and Landau (U.S. Patent No. 4,592,742).

In view of the amendments above, and the remarks below, Applicants respectfully request reconsideration of the rejected claims under 37 C.F.R. § 1.111.

Rejections under 35 U.S.C. § 112

Applicants thank the Examiner for pointing out the insufficient antecedent bases in claims 1, 8, and 12. Appropriate amendments have been made to these claims. In view of the above amendments, applicants respectfully request the withdrawal of the rejection of claims 1-12 under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C § 103

Claims 1-4, 8-11, and 13 were rejected under 35 USC §103(a) as being unpatentable over Mizzy et al. in view of Hogan and Landau. Applicants respectfully traverse this rejection. To establish a *prima facie* case of obviousness, there must be some suggestion or motivation to modify the reference or to combine reference teachings, there must be a reasonable expectation of success, and the prior art reference (or references when combined) must teach or suggest all

the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2142.

Claim 1 and its Dependent Claims

Neither Mizzy, Hogan, nor Landau, either alone or in combination, teach or suggest the needle-free injector device claimed in independent claim 1. Claim 1 recites a marking assembly configured to place a mark on or near an injection site to indicate an injection *has occurred*, the marking assembly being fluidly coupled with the needle-free injection device, such that the marking assembly is activated *upon post-injection venting* of the needle-free injection device

Mizzy discloses a needle-free injector including a syringe assembly and a pressurized gas delivery mechanism. Hogan discloses a needle injector coupled with a marking device. Landau discloses a pressurized hypodermic syringe. However, not only do Mizzy, Hogan, and Landau fail to disclose, teach, or suggest the needle-free injection device of claim 1, Hogan actually teaches away from such a device.

The needle injector of Hogan includes a vaccine dosage syringe and an ink dispenser coupled by a common handle to simultaneously deliver an injection and a marking (the '637 patent, col. 4, ll. 34-52; col. 6, ll. 22-39; Fig. 1). Although the pumping action of the handle may be replaced by actuation of a source of compressed gas, the gas drives movement of both the vaccine and ink dispenser plungers in the same manner as the handle version (the '637 patent, col. 6, ll. 40-51). In a second embodiment of Hogan, a pressurized ink canister is triggered upon contact from the handle (the '637 patent, col.12, ll. 28-50; Figs. 2-4). Consequently, the marking assembly in Hogan is either not fluidly coupled to anything or the syringe and marking

assemblies move together, rather than the marking assembly being fluidly coupled with the needle-free injection device, such that the marking assembly is activated upon post-injection venting of the needle-free injection device. Not only is the marking assembly of Hogan not activated upon post-injection venting, it is also not configured to indicate an injection has already occurred. For example, if the syringe assembly of Hogan was not functioning properly, or was not filled properly, the marking assembly would not be affected since pressurized gas is supplied to the marking assembly directly, rather than upon post-injection venting. Consequently, the marking assembly may produce a mark when an injection has not occurred.

Mizzy, Hogan, and Landau, either individually or in combination, fail to disclose, teach, or suggest the injection device of claim 1. For at least these reasons, applicants respectfully request the withdrawal of the rejection of claim 1 under 35 U.S.C. § 103(a). Claims 2-4 depend from and further limit claim 1 and should therefore be allowed when claim 1 is allowed.

Claim 8 and its Dependent Claims

Without acknowledging the propriety of the rejection of claim 8, and in the interest of furthering prosecution of the application, applicants have amended claim 8 to recite a marking assembly configured to place a mark on or near an injection site to indicate an injection has occurred, the marking assembly being fluidly coupled with the needle-free injection device, such that the marking device is activated by post-injection exhaust gas from the gas delivery mechanism. As noted above, not only do Mizzy, Hogan, and Landau fail to disclose, teach, or suggest the needle-free injection device of amended claim 8, Hogan actually teaches away from such a device. For at least these reasons, applicants respectfully request the withdrawal of the rejection of claim 8 under 35 U.S.C. § 103(a). Claims 9-11 depend from and further limit claim 8 and thus should be allowed when amended claim 8 is allowed.

Claim 13

Without acknowledging the propriety of the rejection of claim 13, and in the interest of furthering prosecution of the application, applicants have amended claim 13 to recite a marking assembly configured to place a mark on or near an injection site to indicate an injection has occurred, and an exhaust gas pathway configured to direct at least a portion of post-injection exhaust gas from the pressurized gas delivery mechanism to the marking assembly. As noted above, not only do Mizzy, Hogan, and Landau fail to disclose, teach, or suggest the needle-free injection device of amended claim 13, Hogan actually teaches away from such a device. For at least these reasons, applicants respectfully request the withdrawal of the rejection of claim 13 under 35 U.S.C. § 103(a).

New Claim 14 and its Dependent Claims

New claims 14-20 are directed to a marking assembly configured to place a mark on or near an injection site to indicate an injection has occurred, the marking assembly being fluidly coupled with the gas delivery mechanism, such that the marking assembly is activated upon post-injection venting of the gas delivery mechanism. For the reasons discussed above, these claims are believed to be allowable.

Conclusion

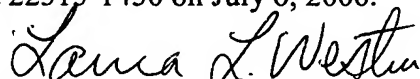
It is believed that the subject patent application has been placed in condition for allowance, and such action is respectfully requested. If the Examiner has any questions or concerns, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.



The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 11-1540.

CERTIFICATE OF MAILING

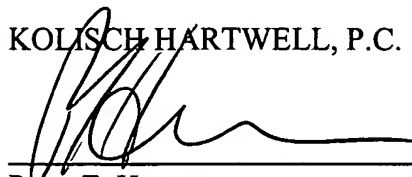
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on July 6, 2006.



Laura L. Westin

Respectfully submitted,

KOLISCH HARTWELL, P.C.



Peter E. Heuser

Registration No. 27,902

Customer No. 23581

Attorney for Applicants

520 S.W. Yamhill Street, Suite 200

Portland, Oregon 97204

Telephone: (503) 224-6655

Facsimile: (503) 295-6679